

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference AY/2007.3442	FOR FURTHER ACTION	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/SG2007/000398	International filing date (<i>day/month/year</i>) 17 November 2007	(Earliest) Priority Date (<i>day/month/year</i>) 17 November 2006
Applicant AGENCY FOR SCIENCE, TECHNOLOGY AND RESEARCH et al		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of **6** sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of:

☒ The international application in the language in which it was filed.

☐ A translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box No. II).

3. ☒ **Unity of invention is lacking** (See Box No. III).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. **1**

☒ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

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Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
See supplemental sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

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A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

C08F 251/00 (2006.01) *A61F 9/00* (2006.01) *G02C 7/04* (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPIDS, JAPIO, CAPLUS; Key Words: porous, polymer, copolymer, microemulsion, emulsion, surfactant, crosslink, wetting, hyaluronic, dextran, polyvinylpyrrolidone,

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2006/0235162 A1 (MULLER et al) 19 October 2006 See abstract, paragraphs 7, 26 and 96	15-17, 19, 21-25
Y	See abstract, paragraphs 7, 26 and 96	1-25
Y	WO 2006/014138 A1 (AGENCY FOR SCIENCE, TECHNOLOGY AND RESEARCH) 9 February 2006 See whole document	1-25
X	US 2002/0165324 A1 (BOWERS et al) 7 November 2002 See abstract, paragraphs 4, 5 and 13	15, 21-25

☒ Further documents are listed in the continuation of Box C☒ See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"E" earlier application or patent but published on or after the international filing date

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"O" document referring to an oral disclosure, use, exhibition or other means

"&" document member of the same patent family

"P" document published prior to the international filing date but later than the priority date claimed

Date of the actual completion of the international search
07 January 2008

Date of mailing of the international search report

08 FEB 2008

Name and mailing address of the ISA/AU

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C (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2002/039948 A2 (N.V.R. LABS BVI) 23 May 2002 See abstract, page 6 lines 7-12	15, 19, 24
X	US 2005/0271729 A1 (WANG) 8 December 2005 See paragraphs 8 and 37	15, 19, 24, 25
X	US 2005/0148682 A1 (HU et al) 7 July 2005 See abstract, paragraphs 30, 32 and 57	15, 20, 21, 24, 25
X	Patent Abstracts of Japan JP 06-239942 A (ONISHI YASUHIKO) 30 August 1994 See abstract	15, 20, 21, 24, 25
X	Patent Abstracts of Japan JP 63-309914 A (MEITO SANGYO KK et al) 19 December 1988 See abstract	15, 20, 21, 24, 25
E, X	US 2007/0293648 A1 (SHEARDOWN et al) 20 December 2007 See abstract, paragraph 30	15, 19, 24, 25
X	LEACH, Jennie B. et al, "Characterization of protein release from photocrosslinkable hyaluronic acid-polyethylene glycol hydrogel tissue engineering scaffolds", BIOMATERIALS, 26, (2005), pages 125-135	15, 16, 19, 24
X	INSUP, Noh et al, "Effects of cross-linking molecular weights in a hyaluronic acid-poly(ethylene oxide) hydrogel network on its properties", BIOMEDICAL MATERIALS 1 (2006) 116-123	15, 16, 19, 24

Supplemental Box

(To be used when the space in any of Boxes I to IV is not sufficient)

Continuation of Box No: III

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

In assessing whether there is more than one invention claimed, I have given consideration to those features which can be considered to potentially distinguish the claimed combination of features from the prior art. Where different claims have different distinguishing features they define different inventions.

This International Searching Authority has found that there are different inventions as follows:

- Claims 1-14, directed to a method of forming a porous polymeric material and materials formed by the method. It is considered that the method of polymerizing water, a cross-linkable wetting agent, a monomer and a polymerizable surfactant in a bicontinuous microemulsion comprises a first distinguishing feature.
- Claims 15-25, directed to a porous material. It is considered that the transparent polymer matrix defining interconnected pores and having a wetting agent at least partially cross-linked with the matrix comprises a second distinguishing feature.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

The only feature common to all of the claims is a porous polymeric material having a wetting agent crosslinked into the matrix. However this concept is not novel in the light of the citations.

This means that the common feature can not constitute a special technical feature within the meaning of PCT Rule 13.2, second sentence, since it makes no contribution over the prior art.

Because the common feature does not satisfy the requirement for being a special technical feature it follows that it cannot provide the necessary technical relationship between the identified inventions. Therefore the claims do not satisfy the requirement of unity of invention *a posteriori*.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/SG2007/000398

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report				Patent Family Member			
US	2006235162	AR	029901	AU	60143/01	BR	0109416
		CA	2401865	CN	1419656	EP	1266246
		MX	PA02009352	NO	20024557	US	7091283
		US	7238750	US	7268189	US	2001037001
		US	2006160957	WO	0171392	ZA	200207477
WO	2006014138	CN	101018814	EP	1773893	US	2007154522
US	2002165324	EP	0555295	HK	53297	JP	9020814
		SG	43188	US	6420453	US	6423761
		WO	9207885				
WO	0239948	AU	23995/02	CA	2428748	EP	1339349
		US	2005260753	US	2006024373		
US	2005271729	EP	1753787	WO	2005113608		
US	2005148682	AU	49801/99	EP	1095076	US	7279507
		US	2001044482	WO	0002937		
JP	6239942	NONE					
JP	63309914	NONE					
US	2007293648	NONE					
Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.							
END OF ANNEX							

PATENT COOPERATION TREATY

From the:
INTERNATIONAL SEARCHING AUTHORITY

To: Yu Sarn Audrey & Partners 190 Middle Rd, #12-04 Singapore 188979		<h2 style="margin: 0;">PCT</h2> WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)	
Date of mailing <i>(day/month/year)</i>		08 FEB 2008	
Applicant's or agent's file reference AY/2007.3442		FOR FURTHER ACTION See paragraph 2 below	
International application No. PCT/SG2007/000398	International filing date <i>(day/month/year)</i> 17 November 2007	Priority date <i>(day/month/year)</i> 17 November 2006	
International Patent Classification (IPC) or both national classification and IPC Int. Cl. C08F 251/00 (2006.01) A61F 9/00 (2006.01) G02C 7/04 (2006.01)			
Applicant AGENCY FOR SCIENCE, TECHNOLOGY AND RESEARCH et al			

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input checked="" type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input checked="" type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input checked="" type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. +61 2 6283 7999	Date of completion of this opinion 07 January 2008	Authorized Officer CATHY DOUGLAS AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No. (02) 6283 2664
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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

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Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ The international application in the language in which it was filed
 - ☐ A translation of the international application into, _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account **the rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:
 - a. type of material
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

WRITTEN OPINION OF THE
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Box No. II Priority

1. ☐ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43*bis*.1 and 64.1) is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:
The right to the priority claim is found to be valid.

WRITTEN OPINION OF THE
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Box No. IV Lack of unity of invention

1. ☐ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:
- ☐ paid additional fees
 - ☐ paid additional fees under protest and, where applicable, the protest fee
 - ☐ paid additional fees under protest but the applicable protest fee was not paid
 - ☐ not paid additional fees

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

☐ complied with

☒ not complied with for the following reasons:

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

In assessing whether there is more than one invention claimed, I have given consideration to those features which can be considered to potentially distinguish the claimed combination of features from the prior art. Where different claims have different distinguishing features they define different inventions.

This International Searching Authority has found that there are different inventions as follows:

- Claims 1-14, directed to a method of forming a porous polymeric material and materials formed by the method. It is considered that the method of polymerizing water, a cross-linkable wetting agent, a monomer and a polymerizable surfactant in a bicontinuous microemulsion comprises a first distinguishing feature.
- Claims 15-25, directed to a porous material. It is considered that the transparent polymer matrix defining interconnected pores and having a wetting agent at least partially cross-linked with the matrix comprises a second distinguishing feature.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

The only feature common to all of the claims is a porous polymeric material having a wetting agent crosslinked into the matrix. However this concept is not novel in the light of the citations.

This means that the common feature can not constitute a special technical feature within the meaning of PCT Rule 13.2, second sentence, since it makes no contribution over the prior art.

Because the common feature does not satisfy the requirement for being a special technical feature it follows that it cannot provide the necessary technical relationship between the identified inventions. Therefore the claims do not satisfy the requirement of unity of invention *a posteriori*.

4. Consequently, this opinion has been established in respect of the following parts of the international application:

☒ all parts

☐ the parts relating to claims Nos.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-14, 18	YES
	Claims 15-17, 19-25	NO
Inventive step (IS)	Claims	YES
	Claims 1-25	NO
Industrial applicability (IA)	Claims 1-25	YES
	Claims	NO

2. Citations and explanations:

D1 US 2006/0235162; **D2** WO 2006/014138; **D3** US 2002/0165324; **D4** WO 2002/039948;
D5 US 2005/0271729; **D6** US 2005/0148682; **D7** JP 06-239942; **D8** JP 63-309914; **D9** US 2007/0293648;

D10 LEACH, Jennie B. et al, "Characterization of protein release from photocrosslinkable hyaluronic acid-polyethylene glycol hydrogel tissue engineering scaffolds", BIOMATERIALS, 26, (2005), pages 125-135

D11 INSUP, Noh et al, "Effects of cross-linking molecular weights in a hyaluronic acid-poly(ethylene oxide) hydrogel network on its properties", BIOMEDICAL MATERIALS. 1 (2006) 116-123

NOVELTY (N)

D1 discloses copolymers suitable for contact lenses. The copolymers have a hydrophilic monomer which may be any mono-unsaturated compound comprising a substituent. The substituent may be hyaluronic acid (see paragraph 26 line 11), which is a wetting agent within the meaning of the claims. The copolymers are further reacted with an organic compound such as HEMA. Since the polymers are used for contact lenses, transparency and porosity are considered inherent. Thus, D1 destroys the novelty of claims 15-17, 19 and 21-25.

D3 discloses copolymers for contact lenses comprising a diluent monomer and a monomer having a positive charge. The latter monomer is considered to be a "wetting agent" within the meaning of the claims since its effect is to reduce lens water loss. The diluent monomer may be HEMA. The polymers are transparent, and porosity is considered inherent as the polymer is formed into a lens which must be porous to some degree. Thus, D1 destroys the novelty of claims 15 and 21-25.

D4 discloses cross-linked hyaluronic acid-laminin gels. The degree of cross-linking is disclosed to determine porosity and other "desirable properties". Transparency is considered to fall within these properties. Thus, D4 destroys the novelty of claims 15, 19 and 24.

D5 discloses a product comprising hyaluronan cross linked to chitosan. The product can be used for contact lenses, is transparent, and porosity is considered inherent. Further, the polymer films can be used to entrap drugs. Thus, D5 destroys the novelty of claims 15, 19, 24 and 25.

D6 discloses an interpenetrating polymer network hydrogel for use in contact lenses, made by polymerizing monomers and non-ionic polymer, the latter including polyvinylpyrrolidone, which is a wetting agent within the meaning of the claims. The monomers may be HEMA. Thus, D6 destroys the novelty of claims 15, 20, 21, 24 and 25.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

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Box No. VI Certain documents cited

1. Certain published documents (Rules 43bis.1 and 70.10)

<u>Application No. Patent No.</u>	<u>Publication date (day/month/year)</u>	<u>Filing date (day/month/year)</u>	<u>Priority date (valid claim) (day/month/year)</u>
US 2007/0293648 A1	20 December 2007	27 April 2007	28 April 2006

US 2007/0293648 discloses a hyaluronic acid containing biopolymer wherein HA is retained by crosslinking, useful for contact lenses. Thus, all the features of claims 15, 19, 24 and 25 are disclosed.

2. Non-written disclosures (Rules 43bis.1 and 70.9)

<u>Kind of non-written disclosure</u>	<u>Date of non-written disclosure (day/month/year)</u>	<u>Date of written disclosure referring to non-written disclosure (day/month/year)</u>
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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

- a) Claims 6 and 20 lack clarity. It is not clear whether "said wetting agent" in these claims only refers to unbonded wetting agent, or whether PVP and dextran can be cross-linkable wetting agents. It appears from the description that PVP and dextran are unbonded wetting agents (see paragraph 29).
- b) Claim 15 is not fully supported by the description, in that the description only envisages products made by the process of claim 1, whereas claim 15 does not require that the products are made by polymerizing a bicontinuous emulsion using a copolymerizable surfactant.

07/02/2008 08:44 FAX 01 2 0200 2010 11 AUSTRALIA 010/010

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box No. V

Each of D7 and D8 disclose polymers useful for contact lenses made by polymerizing a dextran derivative and an unsaturated acid monomer. Dextran is a wetting agent within the meaning of the claims. Transparency and porosity are considered inherent. Thus, each of D7 and D8 destroy the novelty of claims 15, 20, 21, 24 and 25.

D9 was published after the International Filing Date of the present application – see Box VI.

D10 discloses hyaluronic acid-polyethylene glycol hydrogels. The gels are considered inherently porous and transparent. Thus, D10 destroys the novelty of claims 15, 16, 19 and 24.

D11 discloses porous hyaluronic acid-polyethylene oxide hydrogels, which are considered inherently transparent. Thus, D11 destroys the novelty of claims 15, 16, 19 and 24.

None of D1 or D3-D11 discloses the method of forming a porous polymeric material comprising a crosslinkable wetting agent as defined in claim 1, or a porous, transparent polymer matrix comprising a crosslinked wetting agent and in addition an unbonded wetting agent as defined in claim 18, thus claims 1-14 and 18 are considered novel in view of these documents.

INVENTIVE STEP (IS)

Claims 15-17 and 19-25 are lacking in novelty as above, therefore the subject matter of these claims is also obvious and does not meet the requirements of Article 33(3) of the PCT with regard to inventive step.

D2 discloses a transparent, porous polymer formed from a bicontinuous microemulsion of water, monomer and copolymerizable surfactant. The microemulsion further comprises a drug which is dispersed in the formed polymer or the pores thereof. Paragraph 41 discloses that the drug may be a lubricating agent.

D1 discloses that hyaluronic acid can be polymerized into a copolymer via a mono-unsaturated compound. Thus, it is considered obvious in the light of the combined teachings of D1 and D2 to form a porous product by the method disclosed in D2 with the addition of a cross linkable wetting agent as disclosed in D1. It is also considered obvious to include further unbonded wetting agent into the polymer, since D2 discloses that lubricating agents can be incorporated into the polymer. Dextran, polyvinyl pyrrolidone and hyaluronic acid are well known lubricants (wetting agents) for contact lenses. Thus, claims 1-25 lack an inventive step in view of the obvious combination of D1 and D2.